

**PATENT**

Attorney's Docket No: 27779/34766

Applicant or Patentee: JOSEPH S. PODOLSKI  
Serial or Patent No: 09/154,677  
Filed or Issued: September 17, 1998  
For: IMPROVED COMPOSITIONS FOR THE TREATMENT OF  
MALE ERECTILE DYSFUNCTION

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY  
STATUS (37 CFR 1.9(f) and 1.27(c)) -- SMALL BUSINESS CONCERN**

I hereby declare that I am

- ☐ The owner of the small business concern identified below:
- ☒ An official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN ZONAGEN, INC.

ADDRESS OF BUSINESS 2408 Timberloch Place, B-4  
The Woodlands, Texas 77380

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.12, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third-party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to, and remain with, the small business concern identified above with regard to the invention, entitled IMPROVED COMPOSITIONS FOR THE TREATMENT OF MALE ERECTILE DYSFUNCTION, by inventor Joseph S. Podolski,

described in

- ☐ The specification filed herewith.
- ☒ Application Serial No. 09/154,677, filed September 17, 1998.
- ☐ Patent No. \_\_\_\_\_, issued \_\_\_\_\_.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below \* and no

rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c), if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

**\*NOTE:** *Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27).*

NAME: \_\_\_\_\_  
ADDRESS: \_\_\_\_\_  
☐ INDIVIDUAL      ☐ SMALL BUSINESS CONCERN      ☐ NONPROFIT ORGANIZATION

NAME: \_\_\_\_\_  
ADDRESS: \_\_\_\_\_  
☐ INDIVIDUAL      ☐ SMALL BUSINESS CONCERN      ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING: Joseph S. Podolski  
TITLE OF PERSON OTHER THAN OWNER: President  
ADDRESS OF PERSON SIGNING: Zonagen, Inc.  
2408 Timberloch Place, B-4  
The Woodlands, Texas 77380

SIGNATURE: \_\_\_\_\_

Date: \_\_\_\_\_

**DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY**

As a below named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name; I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **"IMPROVED COMPOSITIONS FOR THE TREATMENT OF MALE ERECTILE DYSFUNCTION,"** the specification of which (check one): ☐ is attached hereto; ☒ was filed on September 17, 1998 as Application Serial No. 09/154,677 and was amended on \_\_\_\_\_ (if applicable); ☐ was filed as PCT International Application No. \_\_\_\_\_ on \_\_\_\_\_ and was amended under Article 19 on \_\_\_\_\_ (if applicable). I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above. I acknowledge the duty to disclose to the Patent and Trademark Office all information known to me to be material to patentability as defined in 37 C.F.R. §1.56.

I hereby claim foreign priority benefits under 35 U.S.C. §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

Priority Claimed

_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
(Application Serial Number)	(Country)	(Day/Month/Year Filed)	Yes	No
_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
(Application Serial Number)	(Country)	(Day/Month/Year Filed)	Yes	No

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below:

_____	_____
(Application Serial Number)	(Day/Month/Year Filed)
_____	_____
(Application Serial Number)	(Day/Month/Year Filed)

I hereby claim the benefit under 35 U.S.C. §120 of any United States application(s) or PCT international application(s) designating the United States of America listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior application(s) in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose to the Office all information known to me to be material to patentability as defined in 37 C.F.R. §1.56 which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

_____	_____	_____
(Application Serial Number)	(Day/Month/Year Filed)	(Status-Patented, Pending or Abandoned)
_____	_____	_____
(Application Serial Number)	(Day/Month/Year Filed)	(Status-Patented, Pending or Abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

**POWER OF ATTORNEY:** I hereby appoint as my attorneys, with full powers of substitution and revocation, to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

Alvin D. Shulman (19,412)  
Owen J. Murray (22,111)  
Allen H. Gerstein (22,218)  
Nate F. Scarpelli (22,320)  
Edward M. O'Toole (22,477)  
Michael F. Borun (25,447)  
Trevor B. Joice (25,542)

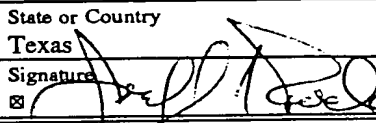
Timothy J. Vezeau (26,348)  
Carl E. Moore, Jr. (26,487)  
Richard H. Anderson (26,526)  
Patrick D. Ertel (26,877)  
James P. Zeller (28,491)  
William E. McCracken (30,195)

Richard A. Schnurr (30,890)  
Anthony Nimmo (30,920)  
Christine A. Dudzik (31,245)  
Jeffrey S. Sharp (31,879)  
Martin J. Hirsch (32,237)  
James J. Napoli (32,361)

Richard M. La Barge (32,254)  
Karl A. Vick (33,288)  
Douglass C. Hochstetler (33,710)  
Robert M. Gerstein (34,824)  
David W. Clough (36,107)  
Richard A. Brandon (37,051)

Send correspondence to: **DAVID W. CLOUGH, ESQ.**

FIRM NAME	PHONE NO.	STREET	CITY & STATE	ZIP CODE
Marshall, O'Toole, Gerstein, Murray & Borun	312-474-6300	6300 Sears Tower 233 South Wacker Drive	Chicago, Illinois	60606-6402

Full Name of First or Sole Inventor <b>Joseph S. Podolski</b>	Citizenship <b>United States</b>
Residence Address - Street <b>3 Pebble Hollow Court</b>	Post Office Address - Street <b>3 Pebble Hollow Court</b>
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State or Country <b>Texas</b>	State or Country <b>Texas</b>
Date <input checked="" type="checkbox"/> <b>Oct. 15, 1998</b>	Signature <input checked="" type="checkbox"/> 

Second Joint Inventor, if any	Citizenship
Residence Address - Street	Post Office Address - Street
City (Zip)	City (Zip)
State or Country	State or Country
Date <input checked="" type="checkbox"/>	Signature <input checked="" type="checkbox"/>

Third Joint Inventor, if any	Citizenship
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City (Zip)	City (Zip)
State or Country	State or Country
Date <input checked="" type="checkbox"/>	Signature <input checked="" type="checkbox"/>

Fourth Joint Inventor, if any	Citizenship
Residence Address - Street	Post Office Address - Street
City (Zip)	City (Zip)
State or Country	State or Country
Date <input checked="" type="checkbox"/>	Signature <input checked="" type="checkbox"/>

## APPLICABLE RULES AND STATUTES

### 37 CFR 1.56. DUTY OF DISCLOSURE - INFORMATION MATERIAL TO PATENTABILITY (Applicable Portion)

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentability defines, to make sure that any material information contained therein is disclosed to the Office.

Information relating to the following factual situations enumerated in 35 USC 102 and 103 may be considered material under 37 CFR 1.56(a).

### 35 U.S.C. 102. CONDITIONS FOR PATENTABILITY: NOVELTY AND LOSS OF RIGHT TO PATENT

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
- (c) he has abandoned the invention, or
- (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraph (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, or
- (f) he did not himself invent the subject matter sought to be patented, or
- (g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

### 35 U.S.C. 103. CONDITIONS FOR PATENTABILITY; NON-OBVIOUS SUBJECT MATTER (Applicable Portion)

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

### 35 U.S.C. 112. SPECIFICATION (Applicable Portion)

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**REVOCATION AND APPOINTMENT OF POWER OF ATTORNEY**

In regard to the following:

**PENDING**

<b>Title</b>	<b>Application</b>	<b>Filed</b>
Methods and Materials for the Treatment of Testosterone Deficiency in Men	60/304,313	7/9/2001
Chitosan Induced Immunopotential	09/173,251	1/14/1998
Combination Therapy for Modulating the Human Sexual Response	09/403,623	11/4/1999
Chitosan Induced Immunopotential	09/433,756	11/4/1999
Combination Therapy for Modulating the Human Sexual Response	09/717,955	11/21/2000
Combination Therapy for Modulating the Human Sexual Response	09/717,995	11/21/2000
Combination Therapy for Modulating the Human Sexual Response	09/717,736	11/21/2000
Improved Compositions for the Treatment of Male Erectile Dysfunction	09/154,677	10/15/1998
Methods for Modulating the Human Sexual Response	09/937,879	10/2/2001
Methods and Formulations for Modulating the Human Sexual Response	09/362,828	7/28/1999
Human Chorionic Gonadotropin Vaccines	09/787,494	6/11/2001

<b>Title</b>	<b>Application</b>	<b>Filed</b>
Method for Treatment of Male Erectile Dysfunction	09/494,627	1/31/2000
Methods for Modulating the Human Sexual Response	09/937,879	10/2/2001
Combination Therapy for Modulating the Human Sexual Response	10/217,575	8/13/2002
Methods and Compositions With Trans-Clomiphene	10/427,768	4/30/2003
Combination Therapy for Modulating the Human Sexual Response	10/462,888	6/17/2003

### **ISSUED**

<b>Title</b>	<b>Patent</b>	<b>Issued</b>
Method of Preparation and Use of Zona Pellucida Antigens & Antibodies for Sterilization and Contraception	4,996,297	2/26/1991
Methods for Modulating the Human Sexual Response	5,565,466	10/15/1996
Methods and Formulations for Modulating the Human Sexual Response	5,731,339	3/24/1998
Method of Preparation and Use of Zona Pellucida Antigens & Antibodies for Sterilization and Contraception	5,820,863	1/13/1998

<b>Title</b>	<b>Patent</b>	<b>Issued</b>
DNA Encoding Mammalian ZPC and Uses Thereof	5,837,497	11/17/1998
Chitosan Induced Immunopotentialiation	5,912,000	6/15/1999
Chitosan Induced Immunopotentialiation	5,965,144	10/12/1999
ZPC Polypeptide	5,976,545	11/2/1999
Chitosan Induced Immunopotentialiation	5,980,912	11/9/1999
Mammalian ZPAS	5,981,228	11/9/1999
Methods and Formulations for Modulating the Human Sexual Response	5,981,563	11/9/1999
Materials and Methods for Immunocontraception	5,989,550	11/23/1999
DNAS Encoding Mammalian ZPBS	6,001,599	12/14/1999
Materials and Methods for Immunocontraception	6,027,727	2/22/2000
Methods and Formulations for Modulating the Human Sexual Response	6,051,594	4/18/2000
Methods and Formulations for Modulating the Human Sexual Response	6,100,286	8/8/2000
Methods and Formulations for Modulating the Human Sexual Response	6,124,337	9/26/2000
Methods and Formulations for Modulating the Human Sexual Response	6,166,061	12/26/2000



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NO. 452 P. 6

Title	Patent	Issued
Method of Preparation and Use for Zona Pellucida Antigens and Antibodies	6,264,953	7/24/2001
Methods and Materials for the Treatment of Prostatic Carcinoma	6,280,742	8/28/2001

ZONAGEN, INC., owners of the above-identified applications and patents hereby revokes all former powers of attorney and appoints, as its attorneys to prosecute this application and to transact all business in the United States Patent and Trademark Office connected therewith:

Attorneys under Customer I.D. No. 22930  
of the law firm of Howrey Simon Arnold & White, LLP

Correspondence Address:

IP Prosecution  
Howrey Simon Arnold & White, LLP  
Box No. 34  
1299 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004-2402

Please address all telephone calls to David W. Clough, Ph.D. at (312) 595-1408 and fax inquiries to (312) 595-2250.

ZONAGEN, INC.

Date: 9/22/03

By: 

Joseph S. Podolski  
President & CEO